

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Richard Twomey, et al.

Serial No.: 10/564,130

Confirmation No.: 6010

Filed : January 10, 2006

Examiner: A.M. Schillinger

For : BONE CEMENT PLUG

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. §1.8

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/Brian S. Tomko/

Appellant Representative

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Dear Sir:

This Appeal Brief is filed in connection with the Notice of Appeal, which was mailed by Appellant to the U.S. Patent & Trademark Office on December 1, 2008.

Real Party In Interest:

The real party in interest for this patent application is DePuy International, Ltd, of Great Britain, UK.

Related Appeals and Interferences:

There are no related appeals or interferences known to Appellants, the Appellants' legal representative, or the Assignee that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

Status of Claims:

Claims 1-3, 5, and 8-20 are pending in this application. Claims 4 and 6 are cancelled. Claims 1-3, 5, and 8-20 have been finally rejected, and are hereby appealed.

Status of Amendments:

No amendments have been filed after the final rejection dated August 1, 2008.

Summary of Claimed Subject Matter:

The subject matter claimed in independent claim 1 is a bone cement plug for fitting into the intramedullary canal within a bone to restrict flow of bone cement during surgery. One embodiment of the claimed device is described generally at page 6, line 22 through page 7, line 28 of the original specification (paragraphs 27-32 of U.S. Application Publication No. 2007/0083212) and is depicted at Figures 1-3. Referring to Figure 1 below, the bone cement plug includes a sleeve 2 (page 6, line 23 of original specification) having a longitudinal axis, an outer surface 10 configured to contact the wall 32 of the canal (page 8, lines 19-21 and Figure 3 below), and inner surfaces configured to define an internal cavity 12 whose diameter decreases from a distal end to a proximal end (page 7, lines 3-5). The internal cavity 12 communicates with an opening 18 formed in the outer surface (page 7, lines 5-6). In Figure 1, below, the proximal end of sleeve 2 is that end near to opening 18.

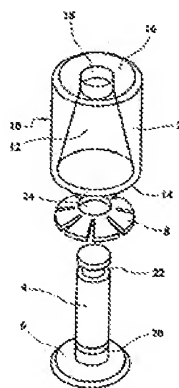


Figure 1

The sleeve 2 is formed of a deformable material (page 5, lines 6-16) and is configured to be expanded transversely to contact the surface 32 of the canal (page 6, lines 27-28; page 8, lines 19-21). Referring to Figure 1, above, and Figure 2, below, the cement plug also includes an expander having a shaft 4 with a distal end and a transverse portion 6 that extends radially from the distal end of shaft 4. The shaft is configured to extend through the opening 18 in sleeve 2 as is shown in Figure 2 below. A washer 8 is configured to be disposed on shaft 4, and has a plurality of radially slots formed therein extending from the outside edge of the washer 8 toward the inside edge thereof. The expander is configured to be movable within cavity 12 in a direction generally along the longitudinal axis from a distal position (see Figure 2) to a proximal position, whereat the washer 8 contacts the internal cavity 12 to cause the wall of the sleeve 2 to expand transversely to contact the surface of the canal 32 (see Figure 3).

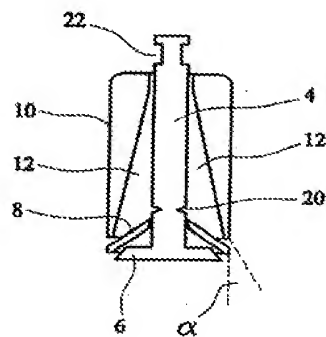


FIG. 2

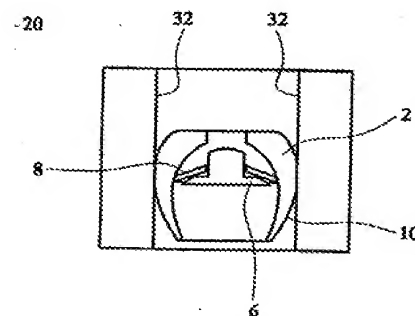


FIG. 3

The subject matter claimed in independent claim 20 is a bone cement plug for fitting into the intramedullary canal within a bone to restrict flow of bone cement during surgery. The bone cement plug includes a sleeve (page 6, line 23 of original specification) that has an outer surface 10 configured to contact the wall of the canal 32 (page 8, lines 19-21 and Figure 3 below), an internal cavity 12 and is formed from a deformable material (page 5, lines 6-16). The bone cement plug also includes an expander that includes a shaft 4 having a distal end and a transverse portion 6 that extends radially from the distal end of shaft 4, and a washer 8 that is configured to be disposed on shaft 4, and has a plurality of radially slots formed therein

extending from the outside edge of the washer toward the inside edge thereof. The expander is movable within cavity 12 from a distal position (see Figure 2) to a proximal position (see Figure 3), whereat washer 8 contacts the internal cavity 12 to cause the wall of the sleeve 2 to expand transversely to contact the surface of the canal 32 (page 6, lines 27-28; page 8, lines 19-21).

Grounds of Rejection to be Reviewed on Appeal:

A) Whether the final rejection stating that claims 1-3, 8, 12, 13 and 17-20 are unpatentable under 35 U.S.C. 103(a) over U.S. Patent No. 5,935,169 (“Chan”) in view of U.S. Patent Publication No. 2003/0065395 (“Ralph”) should be reversed.

B) Whether the final rejection stating that claim 5 is unpatentable under 35 U.S.C. 103(a) over Chan in view of Ralph, as shown in claim 1, and further in view of U.S. Patent No. 6,669,733 (“Spierings”) should be reversed.

C) Whether the final rejection stating that claims 9 and 16 are unpatentable under 35 U.S.C. 103(a) over Chan in view of Ralph, as shown in claim 1, further in view of U.S. Patent No. 7,156,880 (“Evans”) should be reversed.

D) Whether the final rejection stating that claims 10, 11, 14 and 15 are unpatentable under 35 U.S.C. 103(a) over Chan in view of Ralph should be reversed.

Argument:

A. Rejection under 35 U.S.C. 103(a) over U.S. Patent No. 5,935,169 (Chan) in view of U.S. Patent Publication No. 2003/0065395 (Ralph)

Claim 1-3, 8, 12, 13 and 17-19

Applicants submit that the Examiner has failed to make a prima facie case of obviousness with respect to claims 1-3, 8, 12, 13 and 17-19. At the outset, Applicants contend

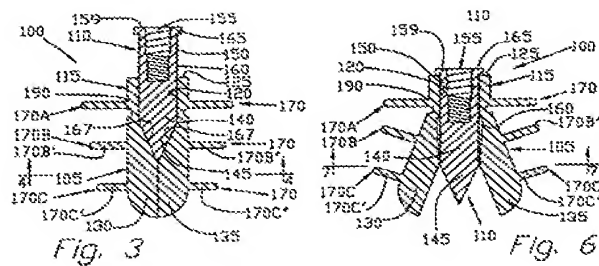
that the Examiner has misunderstood the differences between the claimed invention and the prior art. Further, the Examiner has failed to provide an appropriate supporting rationale for combining the cited references, Chan and Ralph. Finally, if such a combination were considered, it would be inoperable, and would not render the claimed invention unpatentable.

Differences Between Claimed Invention and Prior Art

As to the first contention, the invention of claim 1 is a bone cement plug that includes a deformable sleeve having an internal cavity whose diameter increases from a distal end to a proximal end, an expander having a shaft and a transverse portion that extends radially from the distal end of the shaft, and a washer that has a plurality of slots that extend from the washer's outside edge toward the washer's inside edge. As is shown in Figures 2 and 3, the expander is configured to move within the cavity from a distal position (Figure 2) to a proximal position (Figure 3), whereat the washer contacts the internal cavity to cause the wall of the sleeve to expand transversely to contact the surface of the canal.

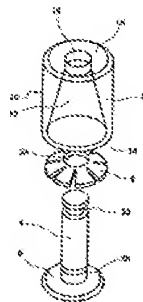
Turning to the cited prior art, the Examiner contends that Chan depicts all of the claimed elements, but for "including washers with the expander". Office Action, page 2, third paragraph. Applicants submit that Chan does not disclose many of the claim elements of claim 1.

Chan is cement plug that is formed of a core 105 having a base portion 115 and a first leg portion 130 and a second leg portion 135 that extend from the base portion. A threaded bore 120 extends axially and distally from a proximal end surface 125 of base portion 115. Threaded bore 120 is adapted to receive expander screw 110 so as to "wedge apart" the first and second leg portions 130, 135, so as to expand core 105 widthwise so as to transform the cross-sectional profile of the distal portion of bone cement plug 100 from circular to elliptical. Such a transformation can be used to secure the bone cement plug in a bone canal. See generally, Chan, column 6, lines 9-25.



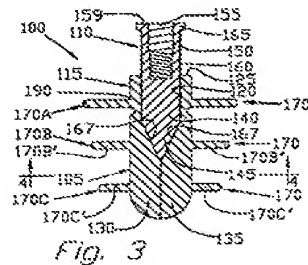
Chan, thus, describes a different type of cement plug, as compared to the claimed invention, one in which an expander screw moves from a proximal position to a distal position to “wedge apart” leg portions 130 and 135 so as to secure the cement plug within a bone canal.

Chan fails to describe many of the elements of claim 1. First, the alleged sleeve 105 of Chan does not have “inner surfaces configured to define *an internal cavity whose diameter decreases from a distal end to a proximal end*”. As is clearly shown in Figures 1 and 2 of the pending application, sleeve 2 includes inner surfaces that define an internal cavity whose diameter decreases from a distal end to a proximal end. The opening 18 defines the proximal end and the opposing end is the distal end.



Turning to Chan, the alleged sleeve 105 does not disclose the claimed element as the alleged internal cavity 120 (described as a bore in Chan) has a *diameter that increases (rather than decreases) from its distal end to its proximal end*. Threaded bore 120 is described as “extend[ing] axially and distally from a proximal end surface 125 of base portion 115”. Chan, col 6, lines 11-13. The cavity 120 of alleged sleeve 105 is thus defined by the proximal portion 115 and the two legs portions 130 and 135. Cavity 120 is threaded to accept expander screw 110, which includes a tapered distal end 145. The cavity 120 of Chan is configured to accept the

tapered end of screw 110, which underscores that the diameter of Chan's cavity increases from a distal end to a proximal end rather than decreases as is claimed in claim 1.



Second, Chan fails to describe the expander of claim 1-- an expander comprising a shaft having a distal end and a ***transverse portion that extends radially from the distal end of the shaft***. The Examiner indicated that element 145 of Chan satisfies the claimed transverse portion. Element 145 is described in Chan as the tapered distal end of screw 110. A tapered portion of a screw tapers inward radially; it does not “extend radially from the distal end of the shaft”.

Third, Chan fails to describe the claimed expander as Chan's expander is not "configured to be movable within the cavity in a direction generally along the longitudinal axis *from a distal position to a proximal position*". Instead, as is described above, Chan's expander, screw 110, moves from a proximal position (near proximal end surface 125) in Figure 2 to a distal position, where it serves to expand leg portions 130 and 135.

Fourth, as the Examiner points out “Chan does not disclose including washers with the expander”. Office Action, page 2, third paragraph. As Chan uses a screw 110 to act against and force apart two leg portions 130, 135, it does not disclose a washer, let alone a washer configured to be disposed on the shaft of the expander that has a plurality of radially slots formed therein extending from the outside edge of the washer toward the inside edge thereof.

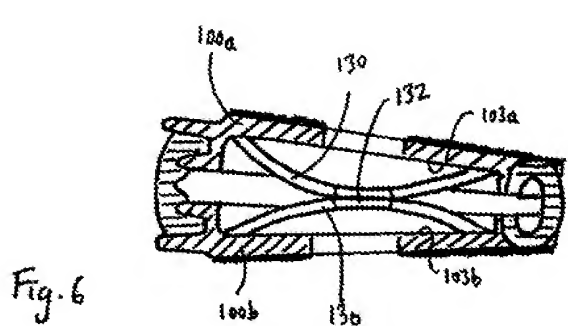
As a result, in addition to the washer limitation, Applicants submit that Chan fails to describe at least three additional claim elements.

Ralph is cited for the proposition that it is obvious to combine the washers of Ralph with Chan. The claim elements not taught by Chan are also not taught by Ralph; nor is the washer limitation. Ralph describes an “artificial disc having a pair of opposing plates for seating against opposing vertebral bone surfaces, separated by at least one spring mechanism.” Ralph, Abstract. Ralph does not describe washers disposed on a shaft as is required by claim 1 of the current invention.

Instead, Ralph describes a number of artificial spine discs, all unrelated to bone cement plugs. One embodiment of Ralph, is reproduced below. The figure depicts an embodiment that

comprises two belleville washers 130 (at least one of which is spirally slotted) that are oriented such that the two central openings 132 of the raised conical ends of the washers 130 are facing one another. The wider ends of the washers 130 are compressibly retained in the interior of the device, between the inner surfaces 103a,103b of the plates 100a,100b. As a result, a compressive load applied to the plates 100a,100b causes the corresponding compression of the belleville washers 130, which in turn causes a restoring force to be applied to the plates 100a,100b.

Ralph, Publn No. 2003/0065395, paragraph 57.



The washers 130 are disposed between two plates, 100a, 100b. They provide a restoring force to the plates which are implanted within the spine and therefore feel compressive loads. Washers 130 of Chan, are not disposed on a shaft as is required by claim 1 of the current invention. Instead they are disposed back to back between the plates. Thus, Ralph does not supply that element that the Examiner relies upon to combine with Chan.

Supporting Rationale for Combining Chan and Ralph

As to the second contention, Applicants submit that the Examiner has failed to provide an appropriate supporting rationale for combining the cited references, Chan and Ralph. The Federal Circuit has stated that “rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). The Examiner states that, though “Chan does not disclose including washers with the expander,” Ralph

teaches a prosthetic device that uses washers in paragraphs 0030-0037 for the purpose of helping the prosthesis to maintain its desired shape. Therefore, it would have been obvious to one skilled in the art at the time the invention was made to use washers with the expander in order to secure the desired shape of the device.

Office Action, page 2, third paragraph. Both Chan and Ralph are devoid of any reason to combine the two references. With respect to the current invention, the slots allow the washer to be deformed from a conical configuration (see Figure 2 above) towards a flattened configuration (see Figure 3 above), as the expander is drawn into the cavity within the sleeve, increasing the transverse dimension of the washer, and therefore also the effective transverse dimension of the expander.

In contrast, as described above, Chan relies upon the direct interaction of the screw expander 110 and the legs leg portions 130, 135 to force apart the leg portions 130 so that they contact the hip canal. Chan does not rely on deformation between the screw and the leg portions to make the cement plug work. There is no need described in Chan for an element that would assist the screw in securing the desired shape of the device.

Conversely, Ralph describes assemblies that

enjoy[] spring-like performance with respect to axial compressive loads, as well as long cycle life to mimic the axial biomechanical

performance of the normal human intervertebral disc. The slots of the belleville washers allow the washers to expand radially as the slots widen under the load, only to spring back into an undeflected shape upon the unloading of the spring.

Ralph uses the washers as a sort of shock absorber that reacts to successive compressive loads the device feels when implanted in the spine. Neither Ralph nor Chan provides a basis or rationale for combining the two. As a result, Applicants submit that one skilled in the art at the time of the invention would not make such a combination.

Combination of Chan and Ralph Is Inoperable

Finally, if such a combination were considered, it would still not render the claimed invention unpatentable. Applicants submit, that even if Chan and Ralph were combined, the combination would be inoperable, and thus one skilled in the art would not do so. Specifically, Chan would not work if a washer was interposed between the screw 110 and the leg portions 130, 135. Screw 110 expands leg portions 130, 135 from a first configuration, shown in Figure 3, above, to the second configuration, shown in Figure 6, above. “The expander screw’s external threads 160 are threadably engageable with the core’s threaded bore 120, whereby clockwise rotation of expander screw 110 relative to core 105 will cause the expander screw to advance into the core so as to wedge apart the core’s first and second leg portions 130, 135 (FIGS. 5-7).” Chan, col 6, lines 34-39. Disposing a washer about the expander screw 110 would render it unable to be threadably engaged with the threaded bore 120, which in turn would prevent expander screw 110 from being moved distally to expand the leg portions 130, 135. Thus, combining a washer with the teachings of Chan would provide an inoperable device.

Thus, for at least the reasons recited above, Applicants submit that the Examiner has failed to make a prima facie case of obviousness with respect to claims 1-3, 8, 12, 13 and 17-19, and request that the Board reverse the rejection.

Claim 20

Applicants submit that the Examiner has failed to make a prima facie case of obviousness with respect to claim 20. The arguments are similar to those made with respect to claims 1-3, 8, 12, 13 and 17-19, above: Applicants contend that the Examiner has misunderstood the differences between the claimed invention and the prior art; failed to provide an appropriate supporting rationale for combining the cited references, Chan and Ralph; and, failed to appreciate that, if such a combination were made, it would be inoperable, and would not render the claimed invention unpatentable.

Claim 20 claims a bone cement plug that includes 1) a sleeve having an outer surface configured to contact the wall of the canal, an internal cavity is formed from a deformable material; 2) an expander with a shaft having a distal end and a transverse portion that extends radially from the distal end of the shaft; and 3) a washer that is configured to be disposed on the shaft that has a plurality of radially slots formed therein extending from the outside edge of the washer toward the inside edge thereof. The expander is movable within the cavity from a distal position to a proximal position, whereat the washer contacts the internal cavity to cause the wall of the sleeve to expand transversely to contact the surface of the canal.

As is described relative to claim 1, Chan fails to describe many of the elements of claim 20. First, Chan fails to describe the expander of claim 20-- an expander comprising a shaft having a distal end and a *transverse portion that extends radially from the distal end of the shaft*. The Examiner indicated that element 145 of Chan satisfies the claimed transverse portion. Element 145 is described in Chan as the tapered distal end of screw 110. A tapered portion of a screw tapers inward radially; it does not “extend radially from the distal end of the shaft”.

Second, Chan fails to describe the claimed expander as Chan’s expander is not “movable within the cavity from a distal position to a proximal position, whereat the washer contacts the internal cavity to cause the wall of the sleeve to expand transversely to contact the surface of the canal”. Instead, as is described above, Chan’s expander, screw 110, moves from a proximal

position (near proximal end surface 125) in Figure 2 to a distal position, where it serves to expand leg portions 130 and 135.

Third, as the Examiner points out “Chan does not disclose including washers with the expander”. Office Action, page 2, third paragraph. As Chan uses a screw 110 to act against and force apart two leg portions 130, 135, it does not disclose a washer, let alone a washer configured to be disposed on the shaft of the expander that has a plurality of radially slots formed therein extending from the outside edge of the washer toward the inside edge thereof.

As a result, in addition to the washer limitation, Applicants submit that Chan fails to describe at least two additional claim elements.

Ralph is cited for the proposition that it is obvious to combine the washers of Ralph with Chan. The claim elements not taught by Chan are also not taught by Ralph; nor is the washer limitation. Ralph describes an “artificial disc having a pair of opposing plates for seating against opposing vertebral bone surfaces, separated by at least one spring mechanism.” Ralph, Abstract. Thus, Ralph does not supply that element that the Examiner relies upon to combine with Chan.

Applicants also submit that similar to the analysis provided with respect to claim 1, the Examiner has failed to provide an appropriate supporting rationale for combining the cited references, Chan and Ralph. Both Chan and Ralph are devoid of any reason to combine the two references. With respect to the current invention, the slots allow the washer to be deformed from a conical configuration (see Figure 2 above) towards a flattened configuration (see Figure 3 above), as the expander is drawn into the cavity within the sleeve, increasing the transverse dimension of the washer, and therefore also the effective transverse dimension of the expander.

In contrast, as described above, Chan relies upon the direct interaction of the screw expander 110 and the legs leg portions 130, 135 to force apart the leg portions 130 so that they contact the hip canal. Chan does not rely on deformation between the screw and the leg portions

to make the cement plug work. There is no need described in Chan for an element that would assist the screw in securing the desired shape of the device.

Conversely, Ralph uses the washers as a sort of shock absorber that reacts to successive compressive loads the device feels when implanted in the spine. Neither Ralph nor Chan provides a basis or rationale for combining the two. As a result, Applicants submit that one skilled in the art at the time of the invention would not make such a combination.

Finally, as described with respect to claim 1, if the combination of Chan and Ralph were considered, it would still not render the claimed invention unpatentable as the combination would be inoperable.

Thus, for at least the reasons recited above, Applicants submit that the Examiner has failed to make a prima facie case of obviousness with respect to claims 1-3, 8, 12, 13 and 17-19, and request that the Board reverse the rejection.

B. Rejection under 35 U.S.C. 103(a) over Chan in view of Ralph, as shown in claim 1, and further in view of U.S. Patent No. 6,669,733 (“Spierings”)

Appellants submit that claim 5 is allowable over Chan in view of Ralph, as shown in claim 1, and further in view of Spierings”. Claim 5 depends from claim 1, which Applicants contend is allowable for reasons described above. As a result, claim 5 is allowable as it depends from claim 1. For at least this reason, Applicants request that the Board reverse the rejection.

C. Rejection under 35 U.S.C. 103(a) over Chan in view of Ralph, as shown in claim 1, further in view of U.S. Patent No. 7,156,880 (“Evans”)

Appellants submit that claim 9 and 16 are allowable over Chan in view of Ralph, as shown in claim 1, and further in view of Evans.

Claim 9

Claim 9 depends from claim 8, which in turn depends from claim 1. Applicants contend claim 9 is allowable for at least the reasons described above in connection with claim 1. Further, as described above, neither Chan nor Ralph describe an expander that comprises a shaft having a distal end and a transverse portion that extends radially from the distal end of the shaft. Neither Chan nor Ralph describe the elements of claim 8 (wherein the shaft and transverse portion of the expander are formed as a single component) or claim 9 (wherein the shaft and the transverse portion of the expander are formed from a resorbable material). The Examiner contends that Evans supplies that teaching and provides that it would have been obvious “to use resorbable materials in order to leave a larger effective porosity”. Applicants are not aware that “leaving a larger effective porosity” is a desirable attribute of either Chan or Ralph. Further, Evans simply discloses an implantable material to promote tissue regeneration that can be resorbable. Evans does not describe a resorbable bone cement plug. For at least the forgoing reasons, Applicants contend that the Examiner has failed to make out a prima facie case with respect to claim 9, and seek reversal of the rejection.

Claim 16

Claim 16 depends from claim 1, and as a result, Applicants contend claim 16 is allowable for at least the reasons described above in connection with claim 1. Neither Chan nor Ralph describe the elements of claim 16 (wherein the sleeve is formed from a resorbable material). The Examiner contends that Evans supplies that teaching and provides that it would have been obvious “to use resorbable materials in order to leave a larger effective porosity”.

Applicants are not aware that “leaving a larger effective porosity” is a desirable attribute of either Chan or Ralph. Evans simply discloses an implantable material to promote tissue regeneration that can be resorbable. Evans does not describe a resorbable bone cement plug. Thus, the Examiner has failed to provide any rational underpinning to the claimed combination. As a result, Applicants contend that the Examiner has failed to make out a prima facie case with respect to claim 16, and seek reversal of the rejection.

D. Rejection under 35 U.S.C. 103(a) over Chan in view of Ralph

Appellants submit that claims 10, 11, 14 and 15 are patentable over Chan in view of Ralph, as claims 10, 11, 14 and 15 ultimately depend from claim 1, which Applicants contend is allowable for reasons described above. Applicants contend that, as the Examiner has not made out a prima facie case of obviousness, Applicants are not burdened with providing further reasons as to why the rejected claims are patentable over the cited combination. For at least these reasons, Applicants request that the Board reverse the rejection.

Conclusion:

As such, for the reasons discussed above, Appellants maintain that the Examiner’s final rejection of claims 1-3, 5, and 8-20 as being unpatentable should be reversed.

Respectfully submitted,

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Dated: March 2, 2009

APPENDIX

1. (Previously Presented) A bone cement plug for fitting into the intramedullary canal within a bone to restrict flow of bone cement during surgery, comprising:

a sleeve having a longitudinal axis, an outer surface configured to contact the wall of the canal, and inner surfaces configured to define an internal cavity whose diameter decreases from a distal end to a proximal end, whereat the internal cavity communicates with an opening formed in the outer surface, the sleeve being formed from a deformable material and configured to be expanded transversely to contact the surface of the canal;

an expander comprising a shaft having a distal end and a transverse portion that extends radially from the distal end of the shaft, the shaft configured to extend through the opening;

a washer configured to be disposed on the shaft, and having a plurality of radially slots formed therein extending from the outside edge of the washer toward the inside edge thereof;

and

wherein the expander is configured to be movable within the cavity in a direction generally along the longitudinal axis from a distal position to a proximal position, whereat the washer contacts the internal cavity to cause the wall of the sleeve to expand transversely to contact the surface of the canal.

2. (Previously Presented) The bone cement plug of claim 1, wherein the sleeve has an end wall at the proximal end thereof.

3. (Previously Presented) The bone cement plug of claim 2, wherein the end wall of the sleeve is formed as a single body with the wall of the sleeve.

4. (Cancelled)

5. (Previously Presented) The bone cement plug of claim 1, wherein the shaft is configured to be frangible at a defined line of weakness.

6-7. (Cancelled)

8. (Previously Presented) The bone cement plug of claim 1, wherein the shaft and transverse portion of the expander are formed as a single component.

9. (Previously Presented) The bone cement plug of claim 8, wherein the shaft and the transverse portion of the expander are formed from a resorbable material.

10. (Previously Presented) The bone cement plug of claim 1, wherein the angle between the inner surface of the wall and the longitudinal axis at the distal end of the sleeve is at least about 20 degrees.

11. (Previously Presented) The bone cement plug of claim 1, wherein the angle between the inner surface of the wall and the longitudinal axis at the distal end of the sleeve is not more than about 50 degrees.

12. (Previously Presented) The bone cement plug of claim 1, wherein the outer surface of the sleeve has surface features to promote engagement with the bone surface of the intramedullary canal.

13. (Previously Presented) The bone cement plug of claim 1, wherein the sleeve has at least one indent in the surface which defines the internal cavity, the indent extending around the internal cavity approximately in a plane that is perpendicular to the axis of the sleeve.

14. (Previously Presented) The bone cement plug of claim 1, wherein the hardness of the material of the sleeve is at least about 30 Shore A.

15. (Previously Presented) The bone cement plug of claim 1, wherein the hardness of the material of the sleeve is not more than about 75 Shore A.

16. (Previously Presented) The bone cement plug of claim 1, wherein the sleeve is formed from a resorbable material.

17. (Previously Presented) An assembly for use in orthopaedic surgery, comprising: a bone cement plug of claim 1 and an instrument for locating the plug in the intramedullary canal within a bone.

18. (Previously Presented) The assembly of claim 17, wherein the expander comprises a shaft that extends generally along the longitudinal axis, and wherein the instrument includes a socket for engaging the shaft on the expander.

19. (Previously Presented) The assembly of claim 17, which includes a drive unit by which the expander can be drawn into the sleeve to cause the expander to move from the distal position to the proximal position.

20. (Previously Presented) A bone cement plug for fitting into the intramedullary canal within a bone to restrict flow of bone cement during surgery, comprising:

- a sleeve having an outer surface configured to contact the wall of the canal, an internal cavity and being formed from a deformable material;

- an expander comprising a shaft having a distal end and a transverse portion that extends radially from the distal end of the shaft; and

- a washer configured to be disposed on the shaft, and having a plurality of radially slots formed therein extending from the outside edge of the washer toward the inside edge thereof,

- wherein the expander is movable within the cavity from a distal position to a proximal position, whereat the washer contacts the internal cavity to cause the wall of the sleeve to expand transversely to contact the surface of the canal.

EVIDENCE APPENDIX

No evidence has been submitted by Appellants pursuant to 37 C.F.R. §§ **1.130**, **1.131**, or **1.132** during the prosecution of this application. Nor has any other evidence been entered by the Examiner and relied upon by Appellants in the appeal.

RELATED PROCEEDINGS APPENDIX

Pursuant to 37 C.F.R. 41.37(c)(1)(ii), Appellants, the Appellants's legal representative, or the Assignee are not aware of any decisions that have been rendered by a court or the Board in any proceeding that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.